

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0235; FRL-9905-56]

Chlorantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide chlorantraniliprole in or on multiple commodities which are identified and discussed later in this document. In addition, this regulation revises existing tolerances in or on papaya, passionfruit, and spice subgroup 19B, and removes several previously established tolerances that will be superseded by tolerances established by this action. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [insert date of publication in the **Federal Register**]. Objections and requests for hearings must be received on or before [insert date 60 days after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0235, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm.

3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090. email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0235 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [insert date 60 days after date of publication in the Federal Register]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0235, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),
 (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL-9386-2), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8158) by DuPont Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, DE 19714. The petition requested that 40 CFR 180.628 be amended by establishing tolerances for residues of the insecticide chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrozole-5-carboxamide, in or on peanuts at 0.06 parts per million (ppm) and peanut, hay at 90 ppm. That document referenced a summary of the petition prepared by DuPont Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Additionally, in the **Federal Register** of July 19, 2013 (78 FR 43115) (FRL-9392-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E8170) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.628 be amended by establishing tolerances for residues of the insecticide chlorantraniliprole in or on fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; nut, tree, group 14-12 at 0.04 ppm; papaya at 4.0 ppm; passionfruit at 4.0 ppm; and onion, green, subgroup 3-07B at 3.0 ppm. The petition also requested that tolerances for spice, subgroup 19B be increased to 40 ppm; and papaya and passionfruit be increased to 4.0 ppm. IR-4 is seeking to raise the tolerance on spice, subgroup 19B based on additional residue data on dill seed; IR-4 is seeking to raise the tolerances on papaya and passionfruit as a result of the request to shorten the existing pre-harvest intervals (PHIs) for the accompanying use directions for these commodities. That document referenced a summary of the petition prepared on behalf of IR-4 by DuPont Crop Protection, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

EPA was petitioned for a tolerance in or on fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; however, the proposed tolerance was incorrectly transcribed in the **Federal Register** Notice of the filing of the petition to propose a tolerance in or on fruit, stone, group 12, except cherry, chickasaw plum, and damson plum. However, the summary available in the docket lists stone fruit group 12-12, except cherry, chickasaw plum, and damson plum. EPA assessed the correct proposed

tolerance on crop group 12-12 rather than crop group 12, for which there is already an established tolerance.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances for several commodities. The reasons for these changes are explained in Unit IV.C. Additionally, IR-4 later withdrew the request to establish a tolerance for tree nut group 14-12.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for chlorantraniliprole

including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with chlorantraniliprole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Chlorantraniliprole does not exhibit immunotoxicity, neurotoxicity, carcinogenicity, or developmental toxicity. Additionally, no mutagenicity concerns were reported in the genotoxicity studies.

In oral and dermal toxicity studies in rats, minimally increased microvesiculation of adrenal cortex was observed mostly in males; however, supporting data demonstrated no effect on the capacity of the adrenal gland to produce corticosterone following stimulation. Therefore, adrenal cortex effects observed in rat studies were not considered adverse.

Chlorantraniliprole does not exhibit prenatal or postnatal toxicity as there were no maternal or fetal effects in studies conducted in rats and rabbits. The relative absence of mammalian hazard may be due in part to chlorantranilprole's selectivity for insect ryanodine receptor (RyR) over mammalian counterparts. In short-term mammalian studies, the most consistent effects are increased liver weights and mild induction of liver enzymes.

Chlorantraniliprole is classified as not likely to be carcinogenic to humans, based on the weight of evidence of the data. No treatment-related tumors were reported in the submitted chronic and oncogenicity studies in rats and mice (18-month carcinogenicity study) or in the subchronic studies in mice, dogs, and rats.

Specific information on the studies received and the nature of the adverse effects caused by chlorantraniliprole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in document "Chlorantraniliprole: Human Health Risk Assessment for Proposed Uses on Green Onion Subgroup 3-07b, and Peanut; for the Requests to Update the Crop Groups of Stone Fruit, Tree Nut, and Spices; to Shorten the Pre-Harvest Intervals for Papaya, Passionfruit, and Mayhaw; and Evaluation of Condition of Registration Data on Rice, Coffee, Strawberry, and Tropical Fruits" at pp. 25-30 in docket ID number EPA-HQ-OPP-2013-0235.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a

population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

http://www.epa.gov/pesticides/factsheets/riskassess.htm.

A summary of the toxicological endpoints for chlorantraniliprole used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of July 27, 2011 (76 FR 44815) (FRL-8875-5).

C. Exposure Assessment

- 1. Dietary exposure from food and feed uses. In evaluating dietary exposure to chlorantraniliprole, EPA considered exposure under the petitioned-for tolerances as well as all existing chlorantraniliprole tolerances in 40 CFR 180.628. EPA assessed dietary exposures from chlorantraniliprole in food as follows:
- i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for chlorantraniliprole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 2003 – 2008 National Health and Nutrition Examination Survey, What We Eat

in America (NHANES/WWEA). As to residue levels in food, EPA assumed tolerance-level residues for the proposed and registered crops, and assumed 100 percent crop treated (PCT) for all commodities. Where processing data indicated a reduction (or no increase) in residue upon processing, the residue level of the raw agricultural commodity (RAC) was used without reduction for the processed commodity, for example mint oil from spearmint. Where processing data indicated an increase in residue in the processed commodity, tolerance-level residues based on tolerances established for those processed commodities were used, e.g., raisins from grapes. However, if residues do not concentrate or where processing data indicated a reduction in residues upon processing, the tolerance for the RAC is used without reduction and a separate tolerance for the processed commodity is not needed. Where adequate processing data do not exist, Dietary Risk Evaluation System (DEEM) default concentration factors were used.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that chlorantraniliprole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for chlorantraniliprole. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for chlorantraniliprole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of chlorantraniliprole. Further

information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/oppefed1/models/water/index.htm.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and PRZM Groundwater (GW) models, the estimated drinking water concentrations (EDWCs) of chlorantraniliprole for chronic exposures for non-cancer assessments are estimated to be 39.87 parts per billion (ppb) for surface water and 207 ppb for groundwater.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. No acute dietary risk assessment was performed because no acute hazard was identified. For chronic dietary risk assessment, the water concentration value of 207 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Chlorantraniliprole is currently registered for the following uses that could result in residential exposures: Sod farms/turf, landscape ornamentals and interiorscapes, and as a termiticide. Residential exposure is expected to occur for short-term and intermediate-term durations; however, due to the lack of toxicity identified for short- and intermediate-term durations via relevant routes of exposure, residential exposure was not assessed. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.

4. Cumulative effects from substances with a common mechanism of toxicity.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found chlorantraniliprole to share a common mechanism of toxicity with any other substances, and chlorantraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlorantraniliprole does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

- 2. Prenatal and postnatal sensitivity. There were no effects on prenatal fetal growth or postnatal development up to the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) in rats or rabbits in the developmental or 2-generation reproduction studies. Moreover, there were no treatment related effects on the numbers of litters, fetuses (live or dead), resorptions, sex ratio, or post-implantation losses. There were no effects on fetal body weights, skeletal ossification, and external, visceral, or skeletal malformations or variations.
- 3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:
 - i. The toxicity database for chlorantraniliprole is complete.
- ii. There is no indication that chlorantraniliprole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factor (UFs) to account for neurotoxicity.
- iii. There is no evidence that chlorantraniliprole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary assessment utilized tolerance-level residues for all crops and assumed that 100 PCT of the proposed and registered crops were treated with chlorantraniliprole.

 Default processing factors were used, as appropriate. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to chlorantraniliprole in drinking water. Moreover, there is a lack of toxicity

via the dermal route, as well as a lack of toxicity over the acute-, short- and intermediateterm via the oral route of exposure. These assessments will not underestimate the exposure and risks posed by chlorantraniliprole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

- 1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, chlorantraniliprole is not expected to pose an acute risk.
- 2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to chlorantraniliprole from food and water will utilize 6.7 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of chlorantraniliprole is not expected.
- 3. Short-term and intermediate-term risk. Short-term and intermediate-term aggregate exposures take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background

exposure level). Because no short-term or intermediate-term adverse effects were identified, the aggregate short-term or intermediate-term risk is the same as the dietary risk, which will not be greater than the chronic aggregate risk.

- 4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chlorantraniliprole is not expected to pose a cancer risk to humans.
- 5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to chlorantraniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, liquid chromatography mass spectrometry (LC/MS/MS); Method DuPont-11374, is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is

recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has not established chlorantraniliprole MRLs for passionfruit, papaya, peanuts, green onions, or spice commodities. EPA cannot harmonize the requested tolerance for stone fruit group 12-12, except cherry, chickasaw plum, and damson plum with the Codex MRL for stone fruit, because the permitted domestic use on these crops in accordance with the approved pesticide label results in residue levels higher than the Codex MRL; EPA will not set tolerances at levels that could result in legally treated food in the United States bearing residues in excess of the approved tolerance.

C. Revisions to Petitioned-For Tolerances

Based on the data supporting the petition, EPA has revised the following proposed tolerance level: Spice subgroup 19B from 40 ppm to 90. The Agency revised this tolerance level based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrozole-5-carboxamide, including its metabolites and degradates, in or on fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; onion, green subgroup 3-07B at 3.0 ppm; peanut, hay at 90 ppm; and peanut at 0.06 ppm. This regulation additionally revises previously established tolerances in or on the following

commodities: Papaya from 2.0 ppm to 4.0 ppm; passionfruit from 2.0 ppm to 4.0 ppm; and spice subgroup 19B from 14 ppm to 90 ppm. Finally, this regulation removes established permanent tolerances or time-limited tolerances for the indirect or inadvertent residues of chlorantraniliprole in or on fruit, stone, group 12, except cherry, chickasaw plum, and damson plum at 4.0 ppm; leek at 0.20 ppm; onion, green at 0.20 ppm; onion, welsh at 0.20 ppm; peanut, hay at 0.20 ppm; and shallots, fresh leaves at 0.20 ppm.

Fruit, stone, group 12, except cherry, chickasaw plum, and damson plum is being removed because the group 12-12 tolerance being established, includes all commodities in group 12 at the same tolerance level. Leek; onion, green; onion, welsh; and shallots, fresh leaves are being removed because each of these commodities are included in the subgroup 3-07B, which is being established at 3.0 ppm, a level higher than the time-limited tolerances for the inadvertent residues of chlorantraniliprole in or on these commodities.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain

any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

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List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 31, 2014

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

- 2. In § 180.628:
- a. Remove the entry "Fruit, stone, group 12, except cherry, chickasaw plum, and damson plum" in the table in paragraph (a).
- b. Add the entries: "Fruit, stone, group 12-12, except cherry, chickasaw plum, and damson plum"; "Onion, green, subgroup 3-07B"; "Peanut, hay"; and "Peanut" to the table in paragraph (a).
- c. Revise the entries "Papaya", "Passionfruit", and "Spice, subgroup 19B" in the table in paragraph (a).
 - d. Remove and reserve paragraph (d).

The amendments read as follows:

§ 180.628 Chlorantraniliprole; tolerances for residues.

(a) * * *

Commodity	Parts per million		
* * *	* *		
Fruit, stone, group 12-12, except	4.0		
cherry, chickasaw plum, and damson			
plum			
* * *	* *		
Onion, green, subgroup 3-07B	3.0		
Papaya	4.0		
Passionfruit	4.0		
Peanut	0.06		
Peanut, hay	90		
* * *	* *		

Spice, subgroup	19B			Ç	90
* *	*	*	*		

* * * * *

(d) Indirect or inadvertent residues. [Reserved]

[FR Doc. 2014-02568 Filed 02/06/2014 at 8:45 am; Publication Date: 02/07/2014]